510(k) SUMMARY

Zimmer Spine

Trinica® and Trinica® Select

Anterior Cervical Plate Systems

AUG 2 9 2013

Date of Summary Preparation:	August 27, 2013
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration Number:	2184052 (Minneapolis)
Company Contact:	Jonathan Gilbert Regulatory Affairs Director Email: Jonathan.Gilbert@Zimmer.com Office: 952.830.6385 Fax: 952.837.6985
Trade Name(s):	Trinica® Anterior Cervical Plate System Trinica® Select Anterior Cervical Plate System
Device Name (Common Name):	Spinal Fixation System
Device Classification:	Class II
Product Code(s):	KWQ
Regulation Number:	21 CFR § 888.3060
Regulation Description:	Spinal Intervertebral Body Fixation Orthosis

Predicate Devices:

For clarification purposes, this is the initial submission for this device modification and has not been previously submitted/withdrawn via a 510(k), PMA or de novo pathway. The current *Trinica® and Trinica® Select Anterior Cervical Plate System* is claimed to be substantially equivalent to the following legally marketed predicate devices:

Trinica® Predicate Device Name	**Submission ID Number**	**Clearance Date**
Trinica® Anterior Cervical Plate System	K012305	August 22, 2001

Trinica® Select Predicate Device Name	**Submission ID Number**	**Clearance Date**
Trinica® Select Anterior Cervical Plate System	K022344	September 24, 2002
Trinica® Anterior Cervical Plate System	K012305	August 22, 2001

General Device Description:

The *Trinica® and Trinica® Select Anterior Cervical Plate Systems* both consist of cervical plates, locking caps, bone screws, and the instruments necessary to implant the specific system. All implant components are made from a titanium alloy (Ti-6Al-4V). Both, the *Trinica® and Trinica® Select Anterior Cervical Plate Systems,* are intended to provide stabilization of the cervical vertebra for various indications (see below). The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and/or self-drilling bone screws using an anterior surgical approach. Bone screws are available for fixed angle or variable angle implantation. The *Trinica® and Trinica® Select Anterior Cervical Plate Systems* are provided non-sterile, are for single use only and are intended to be removed after solid fusion has occurred.

The only difference between the two systems is the *Trinica® Select* system has smaller width cervical plates to accommodate smaller anatomical structures. The locking cap for the *Trinica® Select* system required a reduction to diameter and height to accommodate reduced lateral profile cervical plate.

Indications for Use:

The Trinica® and Trinica® Select Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at level C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Summary of Technological Characteristics:

The current *Trinica® and Trinica® Select Anterior Cervical Plate Systems* share the same technological characteristics to their cleared predicate devices as described in K012305 and K022344, Trinica® and Trinica® Select Anterior Cervical Plate Systems. The characteristics include the same general design, same materials, same range of sizes, substantially equivalent performance characteristics and the same intended use.

The current and predicate *Trinica® and Trinica® Select Anterior Cervical Plate Systems* both consist of cervical plates, locking caps, bone screws, and the instruments necessary to implant the specific system. All implant components are made from a titanium alloy (Ti-6Al-4V).

The current and predicate *Trinica® and Trinica® Select Anterior Cervical Plate Systems* are intended to provide stabilization of the cervical vertebra for various indications for use, as stated in the section above. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and/or self-drilling bone screw using an anterior surgical approach. Bone screws are available for fixed angle or variable angle implantation. The current and predicate *Trinica® and Trinica® Select Anterior Cervical Plate Systems* are provided non-sterile, are for single use only and are intended to be removed after solid fusion has occurred.

Summary of Performance Testing:

The non-clinical testing included components of the current *Trinica® and Trinica® Select Anterior Cervical Plate Systems*, which were reviewed and tested appropriately for design verification, design validation, biocompatibility and sterilization. The test results conclude the current *Trinica® and Trinica® Select Anterior Cervical Plate Systems* to be substantially equivalent to their predicate devices, Trinica® and Trinica® Select Anterior Cervical Plate Systems.

- Bench testing (static compression bending, dynamic compression bending, and static torsion testing per ASTM F1717) was performed for the subject device and confirmed the product performance of current *Trinica and Trinica Select* is suitable for its intended use: the same intended use as the predicate devices.
- Cadaver lab testing of the current *Trinica and Trinica Select* implants and instruments demonstrates that the system meets the defined intended use(s) and functions as intended.
- Biocompatibility testing ensured the current *Trinica and Trinica Select* instrument materials are biocompatible after manufacturing based on the minor design changes made in comparison to the predicate devices.
- Sterilization, Dry Time and Cleaning testing ensured the current *Trinica and Trinica Select* systems steam sterilization, cleaning and dry time instructions are substantially equivalent to the predicate devices.

The current *Trinica® and Trinica® Select Anterior Cervical Plate Systems* performance, intended use and fundamental scientific technology remain unchanged from their predicate devices. The modifications do not change the stabilization fixation of the cervical vertebra when compared to the predicate devices, Trinica and Trinica Select as described in K012305 and K022344. The fixation element consists of a cervical plate that is attached to the vertebral body of the cervical spine using an anterior approach. The plate implant, with self-tapping and/or self-drilling bone screw, is intended to be removed after solid fusion has occurred.

Substantial Equivalence:

Zimmer Spine considers the current *Trinica® and Trinica® Select Anterior Cervical Plate Systems* product performance to be substantially equivalent to their predicate device, Trinica and Trinica Select as described in K012305 and K022344 because there are no changes to the product performance specifications; device intended use, or device functional scientific technology. The table below provides a substantial equivalence summary:

Product Characteristics	***Current Devices*** **Trinica and Trinica Select**	***Predicate Devices*** **Trinica and Trinica Select**	**Compare**
Device Name(s)	*Trinica® Anterior Cervical Plate System* *Trinica® Select Anterior Cervical Plate System*	*Trinica® Anterior Cervical Plate System* *Trinica® Select Anterior Cervical Plate System*	Identical
Product Code	KWQ	KWQ	Identical
Product Classification	Spinal Intervertebral Body Fixation Orthosis	Spinal Intervertebral Body Fixation Orthosis	Identical
Class	Class II FDA 21 CFR § 888.3060	Class II FDA 21 CFR § 888.3060	Identical
Indications For Use	The Trinica® and Trinica® Select Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at level C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with	The Trinica® and Trinica® Select Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at level C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with	Identical

Product Characteristics	*Current Devices* Trinica and Trinica Select	*Predicate Devices* Trinica and Trinica Select	Compare
	degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions. WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.	degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions. WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.	
Device design	Anterior Cervical Plate System intended to provide stabilization of the cervical vertebra for various indications (see above).	Anterior Cervical Plate System intended to provide stabilization of the cervical vertebra for various indications (see above).	Identical
Fundamental Technology	Spinal intervertebral body fixation orthosis	Spinal intervertebral body fixation orthosis	Identical
Surgical Procedure	Anterior surgical approach	Anterior surgical approach	Identical
Instrumentation	Available (Instruments Added)	Available	Similar
Materials – Implants	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)	Identical
Materials – Plates and Locking Caps	Treated: Titanium Anodization per AMS (Aerospace Material Specification) 2488 Type II.	Treated: Titanium Anodization per AMS (Aerospace Material Specification) 2488 Type II.	Identical
System Packaging – Implants and Instruments	Provided Non-Sterile	Provided Non-Sterile	Identical
Drill Bits and Fixation Pins	Provided Sterile	Provided Sterile	Identical
Sterilization	Steam Sterilization Cycle Time: 4 Minutes Temp: 270°F (132°C)	Steam Sterilization Cycle Time: 15 Minutes Temp: 270°F (132°C)	Similar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

Zimmer Spine, Incorporated
Mr. Jonathan Gilbert
Regulatory Affairs Director
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K132012
Trade/Device Name: Trinica® Anterior Cervical Plate Systems
Trinica® Select Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 28, 2013
Received: July 1, 2013

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K132012

Device Name(s): Trinica® Anterior Cervical Plate Systems
Trinica® Select Anterior Cervical Plate System

Indications for Use

The Trinica® and Trinica® Select Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at level C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

WARNING: These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use ____X_____ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices